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*Admitted only in Maryland
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*Practice Limited to
Federal Agencies

May 9, 2003

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Group Art Unit 1645

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MAY 14 2003

Technology Center 2600

Re: U.S. Utility Patent Application
Appl. No. 09/839,565; Filed: October 17, 2001
For: **PTH Receptor and Screening Assay Utilizing the Same**
Inventors: Gardella *et al.*
Our Ref: 0609.4730000/LBB/M-G

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 (27 pages);
3. Copies of one hundred six (106) cited documents; and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
May 9, 2003
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Lawrence B. Bugaisky
Attorney for Applicants
Registration No. 35,086

Enclosures

SKGF_DC1:131768.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gardella *et al.*

Appl. No. 09/869,565

Filed: October 17, 2001

For: **PTH Receptor and Screening
Assay Utilizing the Same**

Confirmation No. 4604

Art Unit: 1645

Examiner: *To Be Assigned*

Atty. Docket: 0609.473000/LBB/M-G

Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

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Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each document is also provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, concise explanation of the relevance of the non-English language document AN1 cited on Form PTO 1449:

Document AN1, European Patent Publication No. EP 0 464 533 is in the German language. An English language abstract of document AN1 is attached as Document AT28.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates

should not be construed as an admission that the information was actually published on the date indicated.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Lawrence B. Bugaisky
Attorney for Applicants
Registration No. 35,086

Date: May 9 2003

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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0609.4730000/LBB/M-G	APPLICATION NO. 09/869,565
	APPLICANT Gardella et al.	
	FILING DATE October 17, 2001	GROUP 1645

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,086,196	04/25/1978	Tregear			03/28/1975
	AB1	5,217,896	06/08/1993	Kramer et al.			12/30/1988
	AC1	6,417,333 B1	07/09/2002	Bringham et al.			11/24/1999
	AD1	6,495,662 B1	12/17/2002	Gardella et al.			10/20/1999
	AE1	6,537,965 B1	03/25/2003	Bringham et al.			11/23/1999
	AF1	6,541,220 B1	04/01/2003	Juppner et al.			11/30/1999
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	AL1	WO 87/01130	02/26/1987	WIPO			Yes No
	AM1	WO 91/05050	04/18/1991	WIPO			Yes No
	AN1	EP 0 464 533	01/08/1992	Europe			Yes No X
	AO1	EP 0 477 885	04/01/1992	Europe			Yes No
	AP1	WO 92/17602	10/15/1992	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Abou-Samra, A.B., et al., "Phorbol 12-Myristate 13-Acetate and Vasopressin Potentiate the Effect of Corticotropin-releasing Factor on Cyclic AMP Production in Rat Anterior Pituitary Cells," J. Biol. Chem. 262:1129-1136, The American Society for Biochemistry and Molecular Biology, Inc. (1987)
AS	1	Abou-Samra, A.B., et al., "Cyclic Adenosine 3',5'-Monophosphate (cAMP)-Dependent and CAMP-Independent Regulation of Parathyroid Hormone Receptors on UMR 106-01 Osteoblastic Osteosarcoma Cells," Endocrinology 129:2547-2554, The Endocrine Society (1991)
AT	1	Abou-Samra, A.B., et al., "Non-Homologous Sequences of Parathyroid and the Parathyroid Hormone Related Peptide Bind to a Common Receptor on ROS 17/2.8 Cells," Endocrinology 125:2215-2217, The Endocrine Society (1989)

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
0609.4730000/LBB/M-GAPPLICATION NO.
09/869,565APPLICANT
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	EP 0 561 412	09/22/1993	Europe			Yes No
	AM2	GB 2 269 176	02/02/1994	Great Britain			Yes No
	AN2	WO 95/11988	05/04/1995	WIPO			Yes No
	AO2	CA 2,126,132	12/18/1995	Canada			Yes No
	AP2	CA 2,126,299	12/21/1995	Canada			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Asarani, A., et al., "Structurally Diverse N-terminal Peptides of Parathyroid Hormone (PTH) and PTH-related Peptide (PTHrP) Inhibit the Na ⁺ /H ⁺ Exchanger NHE3 Isoform by Binding to the PTH/PTHrP Receptor Type I and Activating Distinct Signaling Pathways," <i>J. Biol. Chem.</i> 271:14931-14936, The American Society for Biochemistry and Molecular Biology, Inc. (1996)
AS	2	Barbier, J.-R., et al., "Bioactivities and Secondary Structures of Constrained Analogues of Human Parathyroid Hormone: Cyclic Lactams of the Receptor Binding Region," <i>J. Med. Chem.</i> 40:1373-1380, American Chemical Society (April 1997)
AT	2	Bennett, D., et al., "Kinetic Characterization of the Interaction of Biotinylated Human Interleukin 5 with an Fc Chimera of its Receptor α Subunit and Development of a ELISA Screening Assay using Real-Time Interaction Biosensor Analysis," <i>J. Molec. Recognition</i> 8:52-58, John Wiley & Sons, Ltd. (1995)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	EP 0 748 817	12/18/1996	Europe			Yes No
	AM3	WO 97/02834	01/30/1997	WIPO			Yes No
	AN3	WO 98/05683	02/12/1998	WIPO			Yes No
	AO3	WO 99/18945	04/22/1999	WIPO			Yes No
	AP3	WO 00/31137	06/02/2000	WIPO			Yes No

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AR	3	Bergwitz, C., et al., "Full Activation of Chimeric Receptors by Hybrids between Parathyroid Hormone and Calcitonin," <i>J. Biol. Chem.</i> 271:26469-26472, The American Society for Biochemistry and Molecular Biology, Inc. (1996)
AS	3	Bergwitz, C., et al., "Residues in the Membrane-spanning and Extracellular Loop Regions of the Parathyroid Hormone (PTH)-2 Receptor Determine Signaling Selectivity for PTH and PTH-related Peptide," <i>J. Biol. Chem.</i> 272:28861-28868, The American Society for Biochemistry and Molecular Biology, Inc. (November 1997)
AT	3	Bisello, A., et al., "Parathyroid Hormone-Receptor Interactions Identified Directly by Photocross-linking and Molecular Modeling Studies," <i>J. Biol. Chem.</i> 273:22498-22505, The American Society for Biochemistry and Molecular Biology, Inc. (August 1998)

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	AL4	WO 00/32775	06/08/2000	WIPO			Yes No
	AM4	WO 00/39278	07/06/2000	WIPO			Yes No
	AN4	WO 01/23427	04/05/2001	WIPO			Yes No
	AO4	WO 01/23521	04/05/2001	WIPO			Yes No
	AP						Yes No

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AR	4	Bowie, J.U., et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science</i> 247:1306-1310, American Association for the Advancement of Science (1990)
AS	4	Caulfield, M.P., et al., "The Bovine Renal Parathyroid Hormone (PTH) Receptor Has Equal Affinity for Two Different Amino Acid Sequences: The Receptor Binding Domains of PTH and PTH-Related Protein Are Located within the 14-34 Region" <i>Endocrinology</i> 127:83-87, The Endocrine Society (1990)
AT	4	Chorev, M., et al., "Modifications of Position 12 in Parathyroid Hormone and Parathyroid Hormone Related Protein: Toward the Design of Highly Potent Antagonists," <i>Biochem.</i> 29:1580-1586, American Chemical Society (1990)

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	AL						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>5</u>	Cleland, J.L., et al., "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation, and Oxidation," Crit. Rev. Ther. Drug Carrier Systems 10:307-377, CRC Press, Inc. (1993)
AS	<u>5</u>	Cohen, F.E., et al., "Analogues of Parathyroid Hormone Modified at Positions 3 and 6. Effects on Receptor Binding and Activation of Adenylyl Cyclase in Kidney and Bone," J. Biol. Chem. 266:1997-2004, The American Society for Biochemistry and Molecular Biology, Inc. (1991)
AT	<u>5</u>	Cunningham, B.C., and Wells, J.A., "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis," Science 244:1081-1085, American Association for the Advancement of Science (1989)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	6	Dautzenberg, F., et al., "Mapping of the ligand-selective domain of the <i>Xenopus laevis</i> corticotropin-releasing factor receptor 1: Implications for the ligand-binding site," <i>Proc. Natl. Acad. Sci. USA</i> 95:4941-4946, National Academy of Sciences (April 1998)
AS	6	de Vos, A.M., et al., "Human Growth Hormone and Extracellular Domain of Its Receptor: Crystal Structure of the Complex," <i>Science</i> 255:306-312, American Association for the Advancement of Science (1992)
AT	6	DeAlmeida, V., and Mayo, K., "Identification of Binding Domains of the Growth Hormone-Releasing Hormone Receptor by Analysis of Mutant and Chimeric Receptor Proteins," <i>Mol. Endocrinol.</i> 12:750-765, The Endocrine Society (May 1998)

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	AL						Yes No
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	AN						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Dempster, D.W., et al., "Anabolic Actions of Parathyroid Hormone on Bone," <i>Endocr. Rev.</i> 14:690-709, The Endocrine Society (1993)
AS	2	Donahue, H.J., et al., "Differential Effects of Parathyroid Hormone and Its Analogues on Cytosolic Calcium Ion and cAMP Levels in Cultured Rat Osteoblast-like Cells," <i>J. Biol. Chem.</i> 263:13522-13527, The American Society for Biochemistry and Molecular Biology, Inc. (1988)
AT	2	Gardella, T.J., et al., "Mutational Analysis of the Receptor-activating Region of Human Parathyroid Hormone," <i>J. Biol. Chem.</i> 266:13141-13146, The American Society for Biochemistry and Molecular Biology, Inc. (1991)

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	8	Gardella, T.J., et al., "Determinants of [Arg ²]PTH-(1-34) Binding and Signaling in the Transmembrane Region of the Parathyroid Hormone Receptor," <i>Endocrinology</i> 135:1186-1194, The Endocrine Society (1994)
AS	8	Gardella, T.J., et al., "Analysis of Parathyroid Hormone's Principal Receptor-Binding Region by Site-Directed Mutagenesis and Analog Design," <i>Endocrinology</i> 132:2024-2030, The Endocrine Society (1993)
AT	8	Gardella, T.J., et al., "Transmembrane Residues of the Parathyroid Hormone (PTH)/PTH-related Peptide Receptor That Specifically Affect Binding and Signaling by Agonist Ligands," <i>J. Biol. Chem.</i> 271:12820-12825, The American Society for Biochemistry and Molecular Biology, Inc. (1996)

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AR	2	Gardella, T.J., et al., "Parathyroid Hormone (PTH)-PTH-related Peptide Hybrid Peptides Reveal Functional Interactions between the 1-14 and 15-34 Domains of the Ligand," J. Biol. Chem. 270:6584-6588, The American Society for Biochemistry and Molecular Biology, Inc. (1995)
AS	2	Gentz, R., et al., "Bioassay for trans-activation using purified human immunodeficiency virus tat-encoded protein: Trans-activation requires mRNA synthesis," Proc. Natl. Acad. Sci. USA 86:821-824, National Academy of Sciences (1989)
AT	2	Gombert, F., et al., "Alanine and D-Amino Acid Scan of Human Parathyroid Hormone," in Peptides: Chemistry, Structure and Biology. Proceedings of the 14th American Peptide Symposium, June 18-23, Kaumaya, P.T.P., and Hodges, R.S., eds., Mayflower Scientific Ltd., Kingswinford, UK, pp. 661-662 (1996)

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AR	10	Guo, J., <i>et al.</i> , "Parathyroid Hormone (PTH)/PTH-Related Peptide Receptor Density Modulates Activation of Phospholipase C and Phosphate Transport by PTH in LLC-PK1 Cells," <i>Endocrinology</i> 136:3884-3891, The Endocrine Society (1995)
AS	10	Hjorth, S., <i>et al.</i> , "Constitutive Activity of Glucagon Receptor Mutants," <i>Mol. Endocrinol.</i> 12:78-86, The Endocrine Society (January 1998)
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AS	22	Suva, L.J., et al., "A Parathyroid Hormone-Related Protein Implicated in Malignant Hypercalcemia: Cloning and Expression," <i>Science</i> 237:893-896, American Association for the Advancement of Science (1987)
AT	22	Szabo, P., "In Situ Hybridization," in <i>Human Chromosomes. Manual of Basic Techniques</i> , Verma, R.S., and Babu, A., eds., Pergamon Press, New York, NY, pp.152-165 (1989)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	24	Turner, P., et al., "Single Mutations Allow the PTH2 Receptor to respond to PTHrP," <i>J. Bone Min. Res.</i> 12:Abs. No. 121, Blackwell Science, Inc. (August 1997)
AS	24	Turner, P.R., et al., "A Putative Selectivity Filter in the G-protein -coupled Receptors for Parathyroid Hormone and Secretin," <i>J. Biol. Chem.</i> 271:9205-9208, The American Society for Biochemistry and Molecular Biology, Inc. (1996)
AT	24	Turner, P.R., et al., "Transmembrane Residues Together with the Amino Terminus Limit the Response of the Parathyroid Hormone (PTH) 2 Receptor to PTH-related Peptide," <i>J. Biol. Chem.</i> 273:3830-3837, The American Society for Biochemistry and Molecular Biology, Inc. (February 1998)

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0609.4730000/LBB/M-G	APPLICATION NO. 09/869,565
	APPLICANT Gardella et al.	
	FILING DATE October 17, 2001	GROUP 1645

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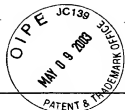
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	25	Unson, C., et al., "Characterization of Deletion and Truncation Mutants of the Rat Glucagon Receptor. Seven Transmembrane Segments are Necessary for Receptor Transport to the Plasma Membrane and Glucagon Binding," J. Biol. Chem. 270:27720-27727, The American Society for Biochemistry and Molecular Biology, Inc. (1995)
AS	25	Van Ostade, X., et al., "Human TNF mutants with selective activity on the p55 receptor," Nature 361:266-269, Macmillan Magazines Ltd. (1993)
AT	25	von Heinje, G., "A new method for predicting signal sequence cleavage sites," Nucl. Acids. Res. 14:4683-4690, IRL Pres Ltd. (1986)

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AR	26	Wilson, I.A., et al., "The Structure of an Antigenic Determinant in a Protein," Cell 37:767-778, MIT (1984)
AS	26	Zhou, A., et al., "Direct mapping of an agonist-binding domain within the parathyroid hormone/parathyroid hormone-related protein receptor by photoaffinity crosslinking," Proc. Natl. Acad. Sci. USA 94:3644-3649, National Academy of Sciences (April 1997)
AT	26	International Search Report for International Patent Application PCT/US99/27656 (mailed May 3, 2000)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	27	International Search Report for International Patent Application PCT/US99/28207 (mailed April 18, 2000)
AS	27	International Search Report for International Patent Application PCT/US00/04716, (mailed October 11, 2000)
AT	27	Dialog File 351, Accession No. 8882525, Derwent WPI English language abstract for European Patent Publication No. EP 0 464 533 (Document AN1), Derwent Information Ltd. (1992)

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